§ 152.95 Citation of all studies in the Agency's files pertinent to a specific data requirement.

An applicant normally may demonstrate compliance for a data requirement by citation of all studies in the Agency's files pertinent to that data requirement. The applicant who selects this cite-all option must submit to the Agency:

(a) A general offer to pay statement having the same wording as that specified in §152.86(c) except that the offer to pay may be limited to apply only to data pertinent to the specific data requirement(s) for which the cite-all method of support has been selected;

(b) A certification that:

(1) For each person who is included on the Data Submitters List as an original data submitter of exclusive use data for the active ingredient in question, the applicant has obtained a written authorization containing the information required by §152.86(a) for the use the any exclusive use study that would be pertinent to the applicant's product; and

(2) For each person included on the current Data Submitters List as an original data submitter of data that are not exclusive use for the active ingredient in question, the applicant has furnished:

(i) A notification of the applicant's intent to apply for registration, including the name of the proposed product, and a list of the product's active ingredients;

(ii) Identification of the specific data requirement(s) for which the offer to pay for data is being made;

(iii) An offer to pay the person compensation to the extent required by FIFRA section 3(c)(1)(F);

(iv) An offer to commence negotiations to determine the amount and terms of compensation, if any, to be paid for use of any study; and

(v) The applicant's name, address, and contact information, including a telephone number and email address.

(c) An acknowledgment having the same wording as that specified in §152.86(d), except that it may be limited to apply only to data pertinent to the specific data requirement(s) for which the cite-all method of support has been selected.

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008; 79 FR 6825, Feb. 5, 2014]

§ 152.96 Claim of data gap.

(a) *When a data gap may be claimed.* Except as provided in paragraph (b) of this section, an applicant may defer his obligation to satisfy an applicable data requirement until the Agency requires the data if no other person has previously submitted to the Agency a valid study that would satisfy the data requirement in question.

(b) *When a data gap may not be claimed*—(1) *Product containing a new active ingredient.* An applicant for registration of a product containing a new active ingredient may not defer his obligation by claiming a data gap unless he can demonstrate to the Agency's satisfaction that the data requirement was imposed so recently that insufficient time has elapsed for the study to have been completed and that, in the public interest, the product should be registered during the limited period of time required to complete the study. Refer to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(7)(C).

(2) *Product not containing a new active ingredient.* An applicant for registration of a product under FIFRA sections 3(c)(7)(A) or (B) (a product not containing a new active ingredient) may not defer his obligation by claiming a data gap if the data are:

(i) Data needed to determine whether the product is identical or substantially similar to another currently registered product or differs only in ways that would substantially increase the risk of unreasonable adverse effects on the environment.

(ii) Efficacy data specific to the product, if required to be submitted to the Agency.

(iii) If a new use is proposed for a product that is identical or substantially similar to an existing product, data to demonstrate whether the new use would substantially increase the risk of unreasonable adverse effects on the environment.

(c) *Approval of application with a data gap claim*—(1) In accordance with

§152.115(a), any registration that is approved based upon a data gap claim shall be conditioned on the submission of the data no later than the time that the data are required to be submitted for similar products already registered.

(2) Notwithstanding paragraph (c)(1) of this section, the Agency will not approve an application if it determines that the data for which a data gap claim has been made are needed to determine if the product meets the requirements of FIFRA sections 3(c)(5) or (7).

[79 FR 6826, Feb. 5, 2014]

§ 152.97 Rights and obligations regarding the Data Submitters List.

(a) Each original data submitter shall have the right to be included on the Agency's Data Submitters List.

(b) Each original data submitter who wishes to have his name added to the current Data Submitters List must submit to the Agency the following information:

(1) Name and current address.

(2) Chemical name, common name (if any) and Chemical Abstracts Service (CAS) number (if any) of the active ingredients(s), with respect to which he is an original data submitter.

(3) For each such active ingredient, the type(s) of study he has previously submitted (identified by reference to data/information requirements listed in part 158 of this chapter), the date of submission, and the EPA registration number, file symbol, or other identifying reference for which it was submitted.

(c) Each applicant not already included on the Data Submitters List for a particular active ingredient must inform the Agency at the time of the submission of a relevant study whether he wishes to be included on the Data Submitters List for that pesticide.

[79 FR 6826, Feb. 5, 2014]

§ 152.98 Procedures for transfer of exclusive use or compensation rights to another person.

A person who possesses rights to exclusive use or compensation under FIFRA section 3(c)(1)(F) may transfer such rights to another person in accordance with this section.

(a) The original data submitter must submit to the Agency a transfer document that contains the following information:

(1) The name, address and state of incorporation (if any) of the original data submitter (the transferor);

(2) The name, address and state of incorporation (if any) of the person to whom the data rights are being transferred (the transferee);

(3) Identification of each item of data transferred including:

(i) The name of the study or item of data;

(ii) Whether the study is an exclusive use study, and, if so, when the period of exclusive use protection expires;

(iii) The name of the person or laboratory that conducted the study;

(iv) The date the study was submitted to the Agency;

(v) The EPA document number assigned to the item of data (the Master Record Identification Number or Accession Number), if known. If not known, the EPA administrative number (such as the EPA Registration Number, petition number, file symbol, or permit number) with which the item of data was submitted, such that the Agency can identify the item of data.

(vi) A statement that the transferor transfers irrevocably to the transferee all rights, titles, and interest in the items of data named;

(vii) A statement that the transferor and transferee understand that any false statement may be punishable under 18 U.S.C. 1001; and

(viii) The names, signatures and titles of the transferor and transferee, and the date signed.

(b) In addition, the original data submitter must submit to the Agency a notarized statement affirming that:

(1) The person signing the transfer agreement is authorized by the original data submitter to bind the data submitter;

(2) No court order prohibits the transfer, and any required court approvals have been obtained; and

(3) The transfer is authorized under Federal, State, and local law and relevant corporate charters, bylaws or partnership agreements.

(c) The Agency will acknowledge the transfer of the data by notifying both